



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/606,201 | 06/25/2003 | Tammy Burd Mehta | 100/05231 | 4356 |

21569 7590 03/10/2006
CALIPER LIFE SCIENCES, INC.
605 FAIRCHILD DRIVE
MOUNTAIN VIEW, CA 94043-2234

EXAMINER

TRAN, MY CHAU T

ART UNIT PAPER NUMBER

1639

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/606,201 | Applicant(s) BURD MEHTA ET AL. | |
| | Examiner MY-CHAU T. TRAN | Art Unit 1639 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 and 12-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-11 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application and Claims Status

1. Applicant's amendment and response filed 12/05/2005 is acknowledged and entered. Claims 2 and 12 have been amended. In addition, the amendment filed includes claims with improper status identifiers. See 37 CFR 1.121 and MPEP § 714. For examples, claims 4-6 are withdrawn claims, yet applicant identifies these claims as "previously presented". These claims were withdrawn from further consideration as being drawn to nonelected species in the Office Action mailed on 09/20/2005. Applicant has identified claim 1 as being "currently amended", yet no marking of the changes has been shown. Although claim 12 is withdrawn claim, but there are marking showing changes and thus claim 12 should be identified as being both "withdrawn/currently amended". Appropriate correction is required.

2. The preliminary amendment filed on 12/23/2003: added claims 2-20.

3. Claims 1-20 are pending.

Election/Restrictions

4. Claims 12-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to *a nonelected invention*, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 07/29/2005.

Art Unit: 1639

5. Applicant is reminded that since applicant has elected to prosecute the product (device of Group I: Claims 1-11, and 17-20), applicants are advised that in accordance with the court decisions in *In re Ochiai*, {71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995)}, and *In re Brouwer* {77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996)}, in the event that a product claim (Group I: Claims 1-11, and 17-20) is found to be allowable, the claim method of use (Group II: Claims 12-16) *which is of the same scope as the allowed product claim* may be rejoined with the allowed product claim.

6. The instant species election requirement is still in effect as there is no allowable generic or linking claim. Applicant has elected the following species for the elected invention (Claims 1-11, and 17-20) in the reply filed on 7/29/2005:

- a. A single specific species of reagents. Applicant elected nucleic acid of claim 3.
- b. A single specific species of beads. Applicant elected DNA coated microspheres of claim 7.
- c. A single specific species of device that is if the device requires a fluid system or not. Applicant elected that the device requires a fluid system.

7. Claims 4-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to *nonelected species*, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/29/2005.

8. Claims 1-3, 7-11, and 17-20 are under consideration in this Office Action.

Priority

9. This instant application is a CON of 09/510,626 filed 02/22/2000, which claims benefit to three provisional applications. They are 60/121,223 filed 02/23/1999, 60/127,825 filed 04/05/1999, and 60/128,643 filed 04/09/1999. This instant application is granted the benefit of priority for 09/510,626 under 35 U.S.C 120, and for all three provisional applications, i.e. 60/121,223, 60/127,825, and 60/128,643, under 35 U.S.C 119(e).

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 1, 2, 8-11, and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Nelson et al. (US Patent 6,007,690; *filing date of 07/30/1996*).

12. Claims 1-3, 7, 9-11, and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Parce et al. (US Patent 5,942,443; *filing date of 06/28/1996*).

13. Claims 1-3, 7, 9-11, and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Parce et al. (US Patent 6,429,025 B1; *filing date of 03/19/1998*).

Art Unit: 1639

Terminal Disclaimer

14. The terminal disclaimer filed on 12/15/2005 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of U.S. Patent No. 6,632,655 B1 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Withdrawn Objection(s) and /or Rejection(s)

15. The rejection under the judicially created doctrine of obviousness-type double patenting of claims 1-3, 7-11, and 17-20 over claims 1, 14, 19, 22, 32-34, 36, 64, and 67 of U.S. Patent No. 6,632,655 B1 has been withdrawn in view of the terminal disclaimer filed on 12/15/2005.

Response to Arguments

16. Applicant's argument directed to the rejection under 35 USC 102(e) as being anticipated by Nelson et al. (US Patent 6,007,690; *filing date of 07/30/1996*) for claims 1, 2, 8-11, and 17-19 was considered but they are not persuasive for the following reasons.

Nelson et al. disclose an integrated microfluidic devices comprises at least an enrichment channel and a main electrophoretic flowpath (see e.g. Abstract; col. 2, lines 48-67; col. 4, lines 3-11). In one type of microfluidic device shown in fig. 3A, the microfluidic device comprises main electrophoretic flowpath (refers to instant claimed reagent flow region)(ref. # 31), a reservoir at each end of the main electrophoretic flowpath (ref. # 32 and 33), and an enrichment channel (refers to instant claimed particle capture region)(ref. # 34) in fluid communication with the main electrophoretic flowpath (see e.g. col. 12, lines 10-24; fig. 3A). As shown in fig. 3A, the enrichment channel is larger than the main electrophoretic flowpath (refers to instant claimed limitation that '*the particle capture region has increased depth relative to the reagent flow region*'). The enrichment channel comprises an inlet, an outlet, and an internal enrichment medium for enriching a particular fraction of a sample (see e.g. col. 4, lines 43-56). The enrichment medium includes media such as beads coated with antibodies (refers to instant claimed a set of particle, and instant claim 2)(see e.g. col. 5, lines 12-49; col. 6, lines 14-29). The depth of the main electrophoretic flowpath is in the range of 1 μ m to 200 μ m (refers to instant claims 9-11)(see e.g. col. 8, lines 46-62). The device also comprises a fluid direction means such as a pump or electrodes (refers to instant claimed fluid direction system, and instant claims 18 and 19)(see e.g. col. 6, line 54 thru col. 7, line 7; col. 8, line 63 thru col. 9, line 10). Although Nelson et al. do not disclose the size of the beads, Nelson et al. disclose using commercially available bead, i.e.

Art Unit: 1639

Dynabead®. The size of these commercially available bead ranges from 1µm to 4.5µm as evidence by the product information of Dynabead®. Thus the device of Nelson et al. anticipates the presently claimed apparatus.

Applicant argues that the reference of Nelson et al. does not anticipate the presently claimed apparatus because a) '*Nelson et al. do not teach a set of particles comprising flowable particles*' and b) '*Nelson et al. are entirely silent with regard to how the beads become positioned within the enrichment channel*'. Thus, the reference of Nelson et al. does not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the teachings of Nelson et al. do anticipate the apparatus of the instant claims. It is the examiner position is that the device of Nelson et al. meets all the structural limitations of the instant claimed apparatus wherein the structural limitations of the instant claimed apparatus comprises a) a body structure with a microscale cavity; b) a sets of particles disposed within the microscale cavity and the particles are beads; c) the microscale cavity comprises a first microchannel with a reagent flow region and a particle capture region; and d) the particle capture region has an increased depth relative to the reagent flow region (see e.g. fig. 3A; col. 4, lines 43-56; col. 12, lines 10-24).

First in response to applicant's argument that '*Nelson et al. do not teach a set of particles comprising flowable particles*', the limitation of "*a set of particles is flowable*" is interpreted as the functional limitation of the instant claimed sets of particles and it does not distinguish the claimed particles from the particles of Nelson et al. See MPEP § 2114, which states:

APPARATUS CLAIMS MUST BE STRUCTURALLY DISTINGUISHABLE FROM THE PRIOR ART
>While features of an apparatus may be recited either structurally or functionally, claims< directed to >an< apparatus must be distinguished from the prior art in terms of structure rather than function. >In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); < In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device

Art Unit: 1639

does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).

And the claimed structural feature of the claimed particles is that they are beads, which is taught by Nelson et al. (see e.g. col. 5, lines 12-49; col. 6, lines 14-29).

Second in response to applicant's argument that the reference fails to show '*how the beads become positioned within the enrichment channel*', the manner in which the claimed particles are use would not differentiate the claimed particles from the particles of Nelson et al. since the particles of Nelson et al. meets all the structural limitation of the claimed particles. See MPEP § 2114, which states:

*MANNER OF OPERATING THE DEVICE DOES NOT DIFFERENTIATE APPARATUS CLAIM
FROM THE PRIOR ART*

A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987) (The preamble of claim 1 recited that the apparatus was "for mixing flowing developer material" and the body of the claim recited "means for mixing ..., said mixing means being stationary and completely submerged in the developer material". The claim was rejected over a reference which taught all the structural limitations of the claim for the intended use of mixing flowing developer. However, the mixer was only partially submerged in the developer material. The Board held that the amount of submersion is immaterial to the structure of the mixer and thus the claim was properly rejected.).

Therefore, the apparatus of Nelson et al. does anticipate the apparatus of the instant claims, and the rejection is maintained.

17. Applicant's argument directed to the rejection under 35 USC 102(e) as being anticipated by Parce et al. (US Patent 5,942,443; *filing date of 06/28/1996*) for claims 1-3, 7, 9-11, and 17-20 was considered but they are not persuasive for the following reasons.

Parce et al. disclose microfluidic devices and methods for performing high-throughput screening assays (see e.g. Abstract; col. 2, lines 36-43; col. 3, lines 3-51). In one type of apparatus shown in figure 3, the microfluidic device comprises a substrate (ref. # 302), a series of parallel reaction channels (ref. # 312-324), sample injection channel (refers to instant claimed reagent flow region)(ref. #304), seeding channel (ref. #306), collection channel (ref. #308), and bead resting wells (ref. #326-338) (refers to instant claimed particle capture region)(see e.g. col. 16, line 1 thru col. 18, line 65; figs. 3 and 4). As illustrated in figures 3 and 4, the bead resting wells that are located at the intersection of

Art Unit: 1639

the sample injection channel and the parallel reaction channels are larger than the sample injection channel and the parallel reaction channels in order retain the bead refers to instant claimed limitation that '*the particle capture region has increased depth relative to the reagent flow region*'. The bead comprises immobilized test compound that include nucleic acids (refers to instant claims 2, 3, and 7)(see e.g. col. 6, line 60 thru col. 7, line 19; col. 16, line 47-52). The dimension of the channels ranges from 1 μm to 500 μm (refers to instant claims 9-11)(see e.g. col. 3, lines 8-10; col. 8, lines 43-57). The device also comprises a fluid direction means such as a pump or electrodes (refers to instant claimed fluid direction system, and instant claims 18 and 19) and a computer system (refers to instant claim 20)(see e.g. col. 12, lines 11-44; col. 21, lines 7-11). Thus the device of Parce et al. anticipates the presently claimed apparatus.

Applicant contends that the reference of Parce et al. does not anticipate the presently claimed apparatus because '*Parce et al. do not teach a microchannel comprising a particle capture region and a reagent flow region, the particle capture region has an increased depth relative to the reagent flow region*'. Thus, the reference of Parce et al. does not anticipate the presently claimed apparatus.

Applicant's arguments are not convincing since the teachings of Parce et al. do anticipate the apparatus of the instant claims. It is the examiner position is that the device of Parce et al. does anticipate the presently claimed apparatus because Parce et al. do '*teach a microchannel comprising a particle capture region and a reagent flow region, the particle capture region has an increased depth relative to the reagent flow region*' (see col. 16, lines 48-58). Parce et al. disclose in fig. 3 that '*In those cases where the test compounds are immobilized on beads, the parallel channels may be optionally fabricated to include bead resting wells (ref. # 326-338) at the intersection of the reaction channels with the sample injection channel (ref. # 304)*' wherein the bead resting wells retain the beads (refers to the claimed particle capture region). The compounds are release from the beads and are directed into the reaction channels (refers to the claimed reagent flow region) by redirecting fluid flows down these reaction channels (see col. 16, lines 59-67). Consequently, it is implied that the structural feature of the bead resting wells would have an increased depth relative to the structural feature of the reaction channels since the

Art Unit: 1639

beads do not enter the reaction channels. Therefore, the teachings of Parce et al. do anticipate the apparatus of the instant claims, and the rejection is maintained.

18. Applicant's argument directed to the rejection under 35 USC 102(e) as being anticipated by Parce et al. (US Patent 6,429,025 B1; *filing date of 03/19/1998*) for claims 1-3, 7, 9-11, and 17-20 was considered but they are not persuasive for the following reasons.

Parce et al. disclose microfluidic devices and methods for performing high-throughput screening assays (see e.g. Abstract; col. 3, line 19 thru col. 4, line 15; col. 10, lines 15-34). In one type of apparatus shown in figure 3, the microfluidic device comprises a substrate (ref. # 302), a series of parallel reaction channels (ref. # 312-324), sample injection channel (refers to instant claimed reagent flow region)(ref. #304), seeding channel (ref. #306), collection channel (ref. #308), and bead resting wells (ref. #326-338) (refers to instant claimed particle capture region)(see e.g. col. 25, line 17 thru col. 28, line 16; figs. 3 and 4). As illustrated in figures 3 and 4, the bead resting wells that are located at the intersection of the sample injection channel and the parallel reaction channels are larger than the sample injection channel and the parallel reaction channels in order retain the bead refers to instant claimed limitation that '*the particle capture region has increased depth relative to the reagent flow region*'. The bead comprises immobilized test compound that include nucleic acids (refers to instant claims 2, 3, and 7)(see e.g. col. 9, lines 12-43; col. 25, line 65 thru col. 26, line 3). The dimension of the channels ranges from 1 μm to 500 μm (refers to instant claims 9-11)(see e.g. col. 3, lines 39-41; col. 16, lines 6-20). The device also comprises a fluid direction means such as a pump or electrodes (refers to instant claimed fluid direction system, and instant claims 18 and 19) and a computer system (refers to instant claim 20)(see e.g. col. 19, lines 48 thru col. 20, line 14; col. 31, lines 14-22). Thus the device of Parce et al. anticipates the presently claimed apparatus.

Applicant alleges that the reference of Parce et al. does not anticipate the presently claimed apparatus because '*Parce et al. do not teach a microchannel comprising a particle capture region and a reagent flow region, the particle capture region has an increased depth relative to the reagent flow region*'. Thus, the reference of Parce et al. does not anticipate the presently claimed apparatus.

Applicant's arguments are not convincing since the teachings of Parce et al. do anticipate the apparatus of the instant claims. It is the examiner position is that the device of Parce et al. does anticipate the presently claimed apparatus because Parce et al. do '*teach a microchannel comprising a particle capture region and a reagent flow region, the particle capture region has*

Art Unit: 1639

an increased depth relative to the reagent flow region' (see col. 25, line 66 thru col. 26, line 3).

Parce et al. disclose in fig. 3 that *'In those cases where the test compounds are immobilized on beads, the parallel channels may be optionally fabricated to include bead resting wells (ref. # 326-338) at the intersection of the reaction channels with the sample injection channel (ref. # 304)'* wherein the bead resting wells retain the beads (refers to the claimed particle capture region). The compounds are release from the beads and are directed into the reaction channels (refers to the claimed reagent flow region) by redirecting fluid flows down these reaction channels (see col. 26, lines 10-20). Consequently, it is implied that the structural feature of the bead resting wells would have an increased depth relative to the structural feature of the reaction channels since the beads do not enter the reaction channels. Therefore, the teachings of Parce et al. do anticipate the apparatus of the instant claims, and the rejection is maintained.

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1639

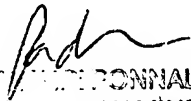
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
March 2, 2006


MY-CHAU T. TRAN
EXAMINER